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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,059	11/30/2001	John B. Ohlrogge	MSU-06689	5499

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MEDLEN & CARROLL, LLP  
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SAN FRANCISCO, CA 94105

EXAMINER
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MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/998,059

Applicant(s)

OHLROGGE ET AL.

Examiner

Ashwin Mehta

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17, 18, 20 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17, 18, 20 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. attached.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objections to the specification of items 6-10 of the Office action mailed December 16, 2004 are withdrawn, in light of the claim amendments.
3. The objections to claims 17, 19, 27, and 30-35 are withdrawn, in light of the claim amendments or cancellations.
4. The rejections of claims 19 and 17-35 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph are withdrawn, in light of the claim amendments.
5. The rejection of claims 20 and 27-29 under 35 U.S.C. 102(b) are withdrawn, in light of the claim amendments or cancellations.

### ***Specification***

6. The Office action mailed June 16, 2005 indicated that sequences on pages 68 and 74 of the specification were not referred to by sequence identifiers. However, this objection was in error, as the preliminary amendment filed July 12, 2002 inserted the appropriate sequence identifiers. However, in the paper submitted June 16, 2005, Applicants again amended these

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sections to recite sequence identifiers, and they are incorrect. It appears that the sequence identifiers that appear in the preliminary amendment were correct, and it is suggested that they be reinserted.

7. The objection to the brief descriptions of Figures 18 and 19 for not reciting labels appearing in the figures is maintained. The amendments to the brief descriptions do not address the objection. The two pages of Figure 18 are labeled as "Figure 18a" and "18b". The three pages of Figure 19 are similarly labeled "19a", "19b", and "19c". The brief descriptions of Figures 18 and 19 must recite --(a-b)-- and --(a-c)--, respectively.

### *Drawings*

8. In response to an objection to the specification that the brief description of Figures 15-17 do not recite the sequence identifiers of the sequences that appear in those figures, Applicants have submitted substitute Figures 15-17 that recite sequence identifiers. However, a comparison with the sequence listing clearly shows that the sequences in the figures do not correspond to the recited sequence identifiers. Correction is required.

## **INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

### **Replacement Drawing Sheets**

Drawing changes must be made by presenting replacement sheets which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments section, or remarks, section of the amendment paper. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). A replacement sheet must include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of the amended

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drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and within the top margin.

### **Annotated Drawing Sheets**

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheet(s) must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

### **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

### ***Claim Rejections - 35 USC § 112***

9. Claims 17, 18, 20, and 22-26 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed December 16, 2004. Applicants traverse the rejection in the papers filed June 16, 2005. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that the specification shows that the inventors were in possession of the claimed invention, and direct attention to portions of the specification that discuss isolation of the sequences in the sequence listing, and their use in methods to isolate additional homologous

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genomic sequences (response, paragraph bridging pages 15-16). However, the specification does not describe the nucleotide sequence of seed-specific promoters that differ in as much as 20% in sequence identity from SEQ ID NO: 1. While the specification generally discusses a method to isolate additional homologous genomic sequences, this does not describe the isolated sequence itself. See Fiers vs. Revel, 25 USPQ 2d (CAFC 1993) at 1606, which states that “[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself”.

Applicants also direct attention to Example 14 of the USPTO’s “Synopsis of Application of the Written Description Guidelines”, and that this example recites an amino acid sequence of SEQ ID NO: 3, and that a claim encompassing sequences having 95% sequence identity to SEQ ID NO: 3 was considered to meet written description requirements. Applicants argue that the same analysis can be applied to the instant claims and that one skilled in the art would conclude that the inventors were in possession of the claimed genus of nucleic acids (response, page 16, last paragraph and page 17, first paragraph). However, the instant claims encompass nucleic acids that differ in sequence identity from SEQ ID NO: 1 by as much as 20%. The specification does not disclose any such structure that remains correlated to the seed-specific transcriptional activity possessed by SEQ ID NO: 1.

Furthermore, claims 17, 18, and 20 now recite “wherein expression from said seed-specific promoter is at least two times greater in seeds than in tissues selected from the group consisting of roots, floral tissue, vascular tissue, and maturing leaf tissue”. Written descriptive

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support for this recitation is lacking in the specification. The recitation is therefore **NEW MATTER** and must be removed from the claims.

Claim amendments are proposed below.

10. Claims 17, 18, 20, and 22-26 are rejected under 35 U.S.C. 1 12, first paragraph, because the specification, while being enabling for the promoter sequence of SEQ ID NO: 1, does not reasonably provide enablement for variants thereof that are at least 80% identical to SEQ ID NO: 1 that retain promoter activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed December 16, 2004. Applicants traverse the rejection in the papers filed June 16, 2005. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that application of the Wands factors indicates the claims are enabled. Applicants argue that it is straightforward to determine sequences that are at least 80% identical to SEQ ID NO: 1, and methods of screening for activity are known in the art (response, paragraph bridging pages 18-19 to page 20, 1<sup>st</sup> full paragraph). However, the specification does not teach those sequences within SEQ ID NO: 1 that are essential for transcriptional activity and seed-specificity. In the absence of this guidance, one skilled in the art is left to randomly change up to any 230 nucleotides of SEQ ID NO: 1 in any manner, to find all sequences in which activity is left unaffected, which is undue experimentation.

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Proposed claim amendments:

It is suggested that the recitation, "80%" in claims 17, 18, and 20 be replaced with --95%-. It is also suggested that the recitation, --non-seed-- be inserted in claims 17 and 18 in line 12 and in claim 20, line 7, before "tissues", and that the recitation, "selected from the group consisting of roots, floral tissue, vascular tissue, and maturing leaf tissue" be deleted from all three claims.

It is also suggested that the specification and drawings be amended as discussed above.

*Summary*

11. Claims 17, 18, 20, and 22-26 remain rejected.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



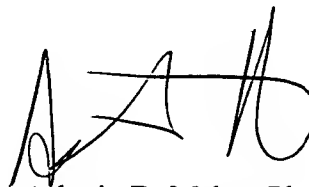
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***Contact Information***

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Jones, can be reached at 571-272-0745. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

August 29, 2005



Ashwin D. Mehta, Ph.D.  
Primary Examiner  
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